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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/133,119 08/12/98 LE J NYU93-01M4AZ

HM12/0619
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EXAMINER

JOHNSON, N

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 06/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/133,119

Applicant(s)

Le

Examiner
Nancy Johnson

Group Art Unit
1642



☒ Responsive to communication(s) filed on Mar 31, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-41 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☒ Claim(s) 4, 6, 12, and 14 is/are allowed.

☒ Claim(s) 1-3, 5, 7-11, 13, and 15-41 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

1. Claims 1, 2, 3, 5, 7, 8 and 17 have been amended.
Claims 18-41 have been added.
Claims 1-41 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The rejection of claims 1-3, 5, 7-11, 13, 15-17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn.
4. The rejection of claims 2-3, 5, 10-11, 13, 17 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claims, is withdrawn.
5. The rejection of claims 1, 7 and 8 under 35 U.S.C. 102(b) as being anticipated either the 1994-1995 Promega Catalog or p.962 of Lehninger's Biochemistry Textbook is withdrawn.
6. The rejection of claims 9 and 15-16 under 35 U.S.C. 102(b) as being anticipated by pages 152-153 of the 1993-1994 New England Biolabs Catalog is withdrawn.
7. The rejection of claims 1, 7, 8, 9 and 15-16 under 35 U.S.C. 102(b) as being anticipated by either of Accession number M32046 (15 June 1990) or N90300 (1 Nov. 1989) is withdrawn.

NEW REJECTIONS

8. The amendment filed 3/31/00 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the

original disclosure is as follows: The amendment to page 34, line 25 of the specification, which inserts low, medium and high stringency condition is an incorporation by reference from the Sambrook and Ausubel references. The applicant states that "relevant portions of Ausubel et al and Sambrook et al are attached as Exhibits A and B." No such Exhibits A and B are found in the applicant's response filed 3/31/00. In the absence of this supporting material, the requested amendment is considered to be new matter.

9. Claims 1-3, 5, 7-11, 13, 15-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3, 7(c), 8(c), 9-11, 15-16, 18-25, 27© and 28© are broadly drawn to polynucleotides (and vectors and methods of manufacture comprising said polynucleotides) that hybridize under various stringency conditions to SEQ ID NO:2, SEQ ID NO:4, the polynucleotide that encodes SEQ ID NO:3 or the polynucleotide that encodes SEQ ID NO:5, wherein said polynucleotide, when expressed along with polynucleotide sequences expressing the appropriate V_H or V_L regions of the cA2 anti-hTNF α antibody and an IgG1 immunoglobulin constant region, encodes a polypeptide that binds to hTNF α .

Claims 5, 13, 17, 26, 29-41 are broadly drawn to polynucleotides (and vectors and methods of manufacture comprising said polynucleotides) that encode polypeptides **comprising "fragments"** SEQ ID NO:3 or SEQ ID NO:5 (amino acid sequences of V_L or V_H regions of the cA2 monoclonal antibody, an anti-hTNF α antibody), said polynucleotides when expressed and paired with the appropriate V_H or V_L region of the cA2 anti-hTNF α antibody and an IgG1 immunoglobulin constant region, bind to hTNF α . Thus, the claim are drawn to polynucleotides that comprise only fragments of the cited SEQ ID NO's.

The specification exemplifies a single species of the broadly claimed genus, the polynucleotide sequence SEQ ID NO:2, which encodes the V_L region of the cA2 monoclonal antibody that binds to hTNF α , and the polynucleotide sequence SEQ ID NO:4, which encodes the

V_H region of the cA2 monoclonal antibody that binds to hTNF α . Because of the highly conserved structure of the immunoglobulin variable region polypeptides and the polynucleotides that encode these regions, and because antibody specificity is controlled by a limited number of amino acid residues scattered throughout the heavy and light variable regions of an immunoglobulin, one of skill in the art can not envision the actual sequences of other polynucleotide sequences based on the common attributes or features cited in the claims. Thus, there is inadequate evidence to lead one of skill in the art that the applicant was in possession of a representative sampling of the claimed genus.

10. Claims 4, 6, 12, 14 are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Johnson whose telephone number is (703) 305-5860. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



NANCY A. JOHNSON, PH.D
PRIMARY EXAMINER

Nancy A. Johnson, Ph.D.

Patent Examiner, Group 1642

June 15, 2000